

REMARKS

In the Office Action dated December 18, 2002, the Examiner: (1) objects to the drawings, the title and a citation in the specification; and (2) rejects claims 23 – 39 under 35 U.S.C. §§ 101, 102, and 112.

With respect to the objections, Applicants: (i) shall submit formal drawings upon the receipt of a Notice of Allowance; (ii) have amended the title as suggested by the Examiner; and (iii) submit that the amendment to the reference to the website on page 14 is not necessary because the website is only being used to refer to the BLAST analysis and this analysis is described in the Altschul *et al.* references that are cited on page 14, lines 24 –25.

The Examiner rejects claims 23 – 39 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. Applicants have amended claims 23 and 29 to include the phrase “substantially isolated and purified.” Support for this amendment may, for example, be found on substitute sheet page 11, lines 26 – 30 of the Specification. In light of this amendment, Applicants submit that this rejection should be withdrawn.

The Examiner rejects claims 23 – 39 under 35 U.S.C. § 112, ¶ 1 as not being enabled. Applicants express no view at this time as to the merits of the Examiner’s position, but in order to further prosecution, have amended the independent claims to specify that functional variants of the protein are capable of binding to α_2M and include a 78% homology over at least thirty amino acids of SEQ ID NO. 6.

Applicants submit that in light of these amendments a rejection under 35 U.S.C. § 112, ¶1 is inappropriate. Page 6, lines 4 –6 describe that a variant sequence is one that “can be used in a vaccine formulation and against which an immune response, preferably a protective immune response . . . is generated on administration of the peptide to an individual.” Page 11, lines 14 –21 discuss procedures for identifying candidates for

generating an immune response, and example 10 illustrates one method. Additionally, page 7, line 6 notes that "homology is calculated on the basis of amino acid identity." Examples of methods for calculating homology are provided on page 14, line 19 through page 15, line 21. These directions enable a person skilled in the art to derive a functional variant. Therefore, Applicants respectfully submit that this rejection should be withdrawn.

The Examiner rejects claims 23 – 39 under 35 U.S.C. § 112, ¶ 2 as being indefinite on two grounds. First, the Examiner asserts that the abbreviation α_2 M is not defined upon its first appearance in the claims. Applicants have amended claims 23 and 29 so as to define α_2 M as an α_2 macroglobulin. Second, the Examiner asserts that the phrase "functional variants" is indefinite. Applicants have amended claims 23 and 29 so as to indicate that the phrase "functional variant" refers to a sequence that is capable of binding to α_2 M and has at least 78% homology to SEQ ID No. 6 over at least thirty amino acids. In light of these amendments, Applicants respectfully submit that the rejection under 35 U.S.C. § 112, ¶ 2 should be withdrawn.

The Examiner rejects previously pending claims 23 –39 under 35 U.S.C. § 102(b) as being anticipated by Lammler *et al.* 1986. Applicants submit that the cited reference does not disclose the sequence of SEQ ID No. 6 or sequences that have 78% homology to SEQ ID No. 6 over thirty amino acids, and the rejection should be withdrawn.

The Examiner also rejects previously pending claims 23 –39 under 35 U.S.C. § 102(b) as being anticipated by Chhatwal *et al.* 1986. Applicants submit that Chhatwal does not disclose the sequence of SEQ ID No. 6 or sequences that have at least 78% homology to SEQ ID No. 6 over at least 30 amino acids, and the rejection should be withdrawn.


Applicants submit that no fee other than the fee for the request for the petition for extension of time is due. However, if any additional fee is due or any overpayment has

Applicants: Bjork *et al.*
Serial No.: 09/847,539
Filed: May 5, 2001
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been made, the Patent Office is authorized to charge deposit account 11-0171 for such sum accordingly.

The Examiner is invited contact the undersigned attorney at the telephone number provided below if he can be of assistance in furthering prosecution.

Respectfully submitted,



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